LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

Developed by

Supported by

TNM-001 COMPOUND

LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

STRUCTURE PLACEHOLDER

TNM-001

Developer(s)

Zhuhai Trinomab Pharmaceutical Co., Ltd.

Originator

https://www.trinomab.com/

China

Zhuhai Trinomab Pharmaceutical Co., Ltd. is a global biopharmaceutical company established in 2015 and headquartered in Zhuhai, China. Focusing on R&D, production, and sales, their proprietary technology, HitmAb®, is a fourth-generation antibody platform for discovering fully human monoclonal antibodies against infectious diseases, autoimmune disorders, malignant tumors, and other human diseases.

Drug structure

TNM-001 COMPOUND

LAPaL

THE LONG-ACTING THERAPEUTICS
PATENTS AND LICENCES DATABASE

STRUCTURE PLACEHOLDER

TNM-001 Structure

Drug information

Associated long-acting platforms

Monoclonal antibodies and antibody drug conjugates

Administration route

Intramuscular

Therapeutic area(s)

Respiratory syncytial virus (RSV)

Use case(s)

Prevention

Use of drug

Ease of administration

Administered by a community health worker
Administered by a nurse
Administered by a specialty health worker

User acceptance

Not provided

Dosage

Available dose and strength

investigated doses are not disclosed

Frequency of administration

Single dose

Maximum dose

Not provided

Recommended dosing regimen

Single dose to at risk infants under 1 year of age who are entering their first RSV season.

Additional comments

Not provided

Dosage link(s)

Not provided

Drug information

Drug's link(s)

Not provided

Generic name

TNM-001

Brand name

Not provided

Compound type

Biotherapeutic

Summary

TNM-001 is an investigational human IgG1 monoclonal antibody (mAb) currently in clinical development for the prevention of respiratory syncytial virus (RSV) infection. Notably, there are no currently approved vaccines or specific antiviral therapies for RSV in China. TNM-001, developed by Trinomab, represents the first domestic long-acting human anti-RSV antibody drug to be independently developed in China. Preclinical studies have demonstrated that TNM-001 exhibits potent RSV neutralising activity and possesses a favourable pharmacokinetic profile, with an extended half-life to provide protection throughout the entire RSV epidemic season. This novel mAb may provide an additional therapeutic option for the prevention of RSV infection in infants and children worldwide.

Approval status

Investigational New Drug (IND) Application of TNM001 injection was approved by China NMPA in July and US FDA in November of 2021.

Regulatory authorities

Unknown

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

General manufacturing requirements and production scale-up for therapeutic monoclonal antibody (mAb) products is primarily focused on pharmacokinetic suitability, formulation stability and the overall maintenance of product quality. Industrial bioprocessing steps can also potentially introduce additional challenges regarding mAb formulation viscosity and aggregation propensity.

Tentative equipment list for manufacturing

Industrial bioreactor vessel with a production volume capacity of between 5-25kL. Continuous disc stack centrifuges for bioreactor harvesting with subsequent membrane and depth filtration for supernatant clarification. Recombinant protein-A chromatography or other suitable affinity capture apparatus followed by two chromatographic polishing steps such as cation- and anion-exchange. Ultrafiltration membrane system to concentrate and formulate the final product.

Manufacturing

MAbs are highly dependent on their structural, chemical and conformational stability for biological activity. Chemical degradation of mAbs during manufacture can lead to the generation of product variants and complex impurity profiles resulting from a wide range of processes, including: N-linked glycosylation, isomerisation, fragmentation, deamidation, oxidation and C-terminal lysine clipping. Additionally prior to packaging, the final product requires close monitoring for the presence of residual contaminants such as endotoxins and pro-inflammatory peptidoglycans.

Specific analytical instrument required for characterization of formulation

Formulation characterisation steps for therapeutic mAb products include (but are not limited to): (1) Identification of post-translational modifications using ion-exchange chromatography and capillary isoelectric focusing, (2) Measurement of concentration dependent aggregation rates via thermal differential scanning calorimetry, sub-visible particle quantitation and size-exclusion chromatography, and (3) Antibody clipping and fragmentation detection by capillary electrophoresis.

Clinical trials

TNM001-302

Identifier

NCT06710925

Link

https://clinicaltrials.gov/study/NCT06710925

Phase

Phase III

Status

Not yet recruiting

Sponsor

Zhuhai Trinomab Pharmaceutical Co., Ltd.

More details

This study is a Phase 3 randomized, double-blind, placebo-controlled study to evaluate the safety, efficacy, and immunogenicity of TNM001 in high-risk infants when entering their RSV season. Approximately 201 infants will be randomized in a ratio of 2:1 to receive TNM001 or placebo. All subjects will be followed for 270 days after dosing. This study will be conducted at approximately 20 sites in China.

Purpose

A Sudy to Evaluate the Efficacy and Safety of TNM001 in High-risk Infants

Interventions

Intervention 1

TNM001

Intervention 2

placebo

Countries

China

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-11-30

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2024-11-29

Estimated Primary Completion Date

2027-11-30

Estimated Completion Date

2027-11-30

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * 1.High risk infants under 1 year of age who are entering their first RSV season at the time of screening. * 2.Subject's legal representative(s) is(are) able to understand and comply with the requirements and procedures of the protocol,including scheduled visits and sample collection. * 3.Subject is available to complete the follow-up period. Exclusion Criteria: * 1. Any fever (\> 38.0°C) or acute illness within 7 days prior to randomization * 2. History of RSV infection * 3. Being hospitalized at the time of randomization * 4. Currently receiving or expected to receive immunosuppressive therapy during the study period. * 5. Renal impairment or hepatic dysfunction * 6. Nervous system disease or neuromuscular disease * 7. Known immunodeficiency including HIV, mother

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

201

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

TNM001-301

Identifier

NCT06083623

Link

https://clinicaltrials.gov/study/NCT06083623

Phase

Phase II/III

Status

Not yet recruiting

Sponsor

Zhuhai Trinomab Pharmaceutical Co., Ltd.

More details

The purpose of this study is to evaluate the efficacy, safety, pharmacokinetics (PK), neutralizing antibody and antidrug antibody (ADA) response for TNM001 in infants entering their first RSV season.

Purpose

A Trial to Evaluate the Efficacy and Safety of TNM001 for the Prevention of Lower Respiratory Tract Infection Caused by Respiratory Syncytial Virus in Infants

Interventions

Intervention 1

TNM001

Intervention 2

placebo

Countries

China

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2023-10-06

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2023-10-11

Estimated Primary Completion Date

2026-05-31

Estimated Completion Date

2026-08-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * 1. Early and mid-term preterm infants (\<35 weeks 0 day GA) and late preterm infants or full-term infants (≥35 weeks 0 day GA) under 1 year of age, with or without Congenital Heart Disease (CHD) or premature infants Chronic Lung Disease (CLD)who are entering their first RSV season at the time of screening. Exclusion Criteria: * 1. Any fever (\> 38.0°C) or acute illness within 7 days prior to randomization * 2. History of RSV infection or active RSV infection prior to, or at the time of, randomization * 3. Drug medication prior to randomization or expected to be treated by medicines during the study period. * 4. Currently receiving or expected to receive immunosuppressive therapy during the study period. * 5. Renal impairment or hepatic dysfunction * 6. Nervous sys

Health status

Negative to : HIV

Study type

Interventional (clinical trial)

Enrollment

2250

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

TNM001-201

Identifier

NCT05630573

Link

https://clinicaltrials.gov/study/NCT05630573

Phase

Phase I/II

Status

Completed

Sponsor

Zhuhai Trinomab Pharmaceutical Co., Ltd.

More details

The purpose of this clinical trial is to evaluate the safety, tolerability and pharmacokinetics (PK) profile of TNM001 injection in healthy preterm and term infants. The main questions it aims to answer are: * the safety and tolerability of TNM001 injection * the pharmacokinetic (PK) profile of TNM001

Purpose

A Study of TNM001 in Chinese Healthy Preterm and Term Infants

Interventions

Intervention 1

Biological: TNM001

Intervention 2

Biological: Placebo

Countries

China

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-10-25

Anticipated Date of Last Follow-up

2024-06-26

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-06-30

Actual Completion Date

2023-06-30

Studied populations

Age Cohort

- Children

Genders

All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Key Inclusion Criteria: 1. Healthy preterm infants and term infants within 1 year old of age. 2. Infants who are in the first RSV infection season at the time of randomization. Key Exclusion Criteria: 1. Any fever or acute illness within 7 days prior to dosing. 2. LRTI prior to randomization. 3. Received any anti-RSV monoclonal antibody or RSV vaccine. 4. Any other circumstances that, in the opinion of the investigator, may interfere with the assessment of the study drug or the interpretation of the study results. 5. The subject is a child of the investigator or his/her subordinate study personnel or relatives or sponsor staff.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

31

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

Excipients

Proprietary excipients used

Not provided

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

Not provided

Residual solvents used

Not provided

Patent info

There are either no relevant patents or these were not yet submitted to LAPaL

Supporting material

Publications

There are no publication

Additional documents

No documents were uploaded

Useful links

- Trinomab RSV monoclonal antibody (TNM001) completes dosing in the first subject
- TNM001 Product Information
- The Investigator Meeting for the Phase III Clinical Trial of Trinomab's TNM001 Injection was Successfully Held

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

Not provided